c) determining if the individual has the genetic basis of Gilbert's Syndrome, and

d) proceeding with the clinical drug trial based on the knowledge of such individuals possessing or not possessing the genetic basis of Gilbert's Syndrome.

3. (Three Times Amended) The method of claim 2 wherein the sample contains DNA from the individual.

4. (Three Times Amended) The method of claim 2 wherein the method further comprises a step:

eliminating individuals having the genetic basis of Gilbert's Syndrome from the clinical drug trial.

5. (Three Times Amended) The method of claim 2 wherein the method further comprises the step:

selecting individuals having the genetic basis for Gilbert's Syndrome for the clinical drug trial.

6. (Three Times Amended) The method of claim 2 further comprising:

e) interpreting the results of the clinical drug trial incorporating data regarding the genetic basis of Gilbert's Syndrome in distinguishing adverse effects of a drug.

7. (Three Times Amended) The method of claim 2 wherein the method comprises the steps of:

a) isolating DNA from the sample,

b) amplifying a DNA region indicating the genetic basis for Gilbert's Syndrome to form DNA fragments,

c) isolating the amplified DNA fragments, and

d) identifying individuals having the genetic basis of Gilbert's Syndrome.

8. (Three Times Amended) The method of claim 7 wherein step b) the DNA is amplified using a polymerase chain reaction (PCR) using a radioactively labeled pair of nucleotide primers.

9. (Three Times Amended) The method of claim 7 wherein the DNA region indicating the genetic basis of Gilbert's Syndrome is a gene encoding UDP-glucuronosyltransferase (UGT).

10. (Three Times Amended) The method of claim 7 wherein the DNA to be amplified is in an upstream promoter region of the UGT 1*1 exon 1.

11. (Three Times Amended) The method of claim 7 wherein the DNA to be amplified includes a region between -35 and -55 nucleotides at the 5' end of UGT 1*1 exon.

12. (Three Times Amended) A kit for screening participants for clinical drug trials, wherein the kit comprises primers for amplifying a region of DNA indicating a genetic basis of Gilbert's Syndrome, and the kit further comprising instructions directing a user of the kit that the kit should be used to identify drug trial participants having the genetic basis for Gilbert's Syndrome.

13. (Three Times Amended) Primers for use in amplifying the DNA region in the method of claim 7, the primers comprising primer pairs, AB or CD as follows:

A/B: (A,5' - AAGTGAACTCCCTGCTACCTT-3' (SEQ ID NO:1),

B,5' -CCACTGGATCAACAGTATCT-3' (SEQ ID NO:2) or

C/D: (C,5' -GTCACGTGACACAGTCAAAC-3' (SEQ ID NO:3);

D 5' -TTTGCTCCTGCCAGAGGTT-3' (SEQ ID NO:4)).

Please add the following new claim:

14. (Newly Added) The method of claim 2 wherein the sample is a blood sample or a buccal smear sample.